K130069

APR 5 2013

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: January 8th, 2013

Submitter: GE Healthcare, (GE Medical Systems SCS)
283 rue de la MINIERE
78530 Buc, FRANCE

Primary Contact Person: Ning WEN
Regulatory Affairs Leader
GE Healthcare, (GE Medical Systems SCS)
Tel: (+33)-1-3070-5668
Fax: (+33) 1-3070-4670

Secondary Contact Person: Carol ALLOIAN
Regulatory Affairs Leader
GE Healthcare
Tel: (224) 280-1008
Fax: (847) 589-8524

Device: Trade Name: **Innova EPVision 2.0**
Common/Usual Name: Picture Archiving and Communications System
Classification Names: 21CFR 892.2050, Class II
Product Code: LLZ

Predicate Device(s): K092639, **Innova Vision** Applications (including **Innova EPVision**)

Reference Device(s): K111200, CardioLab System (from GE Healthcare)

Device Description: ***Innova EPVision 2.0*** is the new version of *Innova EPVision* software, which is part of the *Innova Vision Applications* [K092639] software. Innova EPVision 2.0, as all Innova Vision Applications image processing algorithms, is executed on a hardware platform called *Advantage Workstation* (AW) [K110834].

It can perform the following functions:

Functions inherited from *Innova EPVision*:

- Superimpose the segmented DICOM 3D XA, CT, MR dataset on radioscopic or radiographic image of the same anatomy, obtained on an *Innova* Fluoroscopic X-ray system [K113034].
- Register the segmented DICOM 3D XA, CT, MR dataset with radioscopic or radiographic images obtained on an *Innova* Fluoroscopic X-ray system for interventional procedures.
- Image stabilization features such as ECG gated display or motion tracking in the image.
- Capability to load planning data, deposited on the 3D model in *Volume Viewer* [K041521], such as 3D landmarks, ablations lines, and to display them on the 3D-2D fused image to support the physician during procedures.
- Marking points of interest of different size and color during the procedures.
- The frequently used functions are also available from tableside on the Innova Central Touch Screen to provide efficient workflow during the interventional procedures.

Innova EPVision 2.0 can perform additionally the following functions:

- Import electrophysiology (EP) data digitized and processed on the *CardioLab* system [K111200] and use them to color-code EP recording points on 3D model of the visualized anatomy in order to support catheter/device guidance during cardiac electrophysiology interventional procedures.
- Catheter tip detection to help locate the catheter tip on the 2D X-ray image. The user can modify or correct the automatically proposed tip location anytime.
- 3D side viewer allowing the user to freely rotate the 3D model independently from the Fluoro image and the gantry angulation.

Innova EPVision 2.0, as Innova EPVision targets clinical indication for interventional cardiology procedures and in particular cardiac electrophysiology procedures.

Intended Use: **Innova EPVision 2.0** software application is intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.

Indication for Use: **Innova EPVision 2.0** software application is intended to enable users to load, overlay and register in real time 3D datasets with radioscopic or radiographic images of the same anatomy. Electrophysiological signal information is imported and used to color-code these 3D datasets in order to support catheter/device guidance during cardiac electrophysiology interventional procedures.

Technology: Same as predicate device, *Innova EPVision 2.0* is a software application that executes on the *Advantage Workstation* (AW) review workstation [K110834]. The live Innova fluoroscopic images, as well as the necessary exam data, are transmitted from the *Innova* Digital Fluoroscopic Imaging System [K113034] to the AW through a dedicated link. The 3D datasets previously acquired (from XA, CT and MR) are loaded from the AW database. The application fuses the live fluoroscopic images with the 3D dataset. The 3D-2D fusion and the user interface of the application are displayed on the AW main screen, which is distributed identically in Control Room and in Exam Room by a video splitter of Innova system.

Additionally, upon request Innova EPVision 2.0 can receive digitized electrophysiology signals from the CardioLab recording system [K111200] and display them in its signal window. Innova EPVision 2.0 performs automatic measurements on the received mapping channel signal (local activation time [ms] (LAT) and/or voltage amplitude [mV]) and allows the user to manually adjust the measurements with the mouse. Innova EPVision 2.0 marks the point of measurement on the 3D model and color-codes its surrounding area based on the measurement values and thereby allows the user to create step by step 3D electroanatomical maps of cardiac arrhythmias.

Same as predicate device, the frequently used functions are available from the exam room on the Innova Central Touch Screen. This user interface is controlled by the application through the Innova Ethernet network.

The *Innova EPVision 2.0* application employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The *Innova EPVision 2.0* complies with NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set and with voluntary standards IEC 60601-1-4 (2000), IEC 62304 (2006) and IEC 62366 (2007).

The following quality assurance measures were applied to the development of the software application:

- Risk Management
- Requirements Reviews
- Design Reviews
- Performance and Safety testing (Verification)
  The Verification Tests of the Innova EPVision 2.0 were performed in accordance with device Design Verification Plan and with device Verification Procedure, at 3 levels:
  - Software Unit Testing (Unit Test Verification)
  - Software Integration Testing (Integration Verification)
  - System Testing (System Verification)

  The verification tests were performed to check whether the application works as required and whether the risk mitigations have been correctly implemented. Performance testing consists of tests which measured the features and functions behavior supporting the user needs and ensured the physical characteristics of the proposed device. The Verification confirms that the Design Output meets the Design Input (Product Specifications) requirements.
- Final acceptance testing (Validation)
  The Validation Tests of the Innova EPVision 2.0 were executed in accordance with device Design Validation Plan and with device Validation Procedure. The Validation tests ensure that the proposed device fulfills the requirement of the user needs and intended use, the risk mitigation and the product labeling are effective.

Summary of Clinical Tests:

The subject of this premarket submission, *Innova EPVision 2.0*, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the *Innova EPVision 2.0* to be as safe and as effective as its predicate device, and its performance is substantially equivalent to the predicate device.

This conclusion is based on:

- *Innova EPVision 2.0* application does not introduce substantially new indications for use. *Innova EPVision 2.0* application works within the predicate's Intended Use and Indication for Use.
- *Innova EPVision 2.0* application does not raise new issues of safety and effectiveness.
- *Innova EPVision 2.0* application does not introduce new fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

NING WEN
REGULATORY AFFAIRS LEADER
GE HEALTHCARE
283 RUE DE LA MINIERE
BUC 78530
FRANCE

Re: K130069
Trade/Device Name: Innova EPVision 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 27, 2013
Received: March 29, 2013

Dear Mr. Wen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

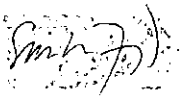
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K130069**

Device Name: **Innova EPVision 2.0**

Indications for Use:

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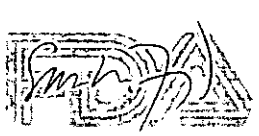
Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130069